

with a certain characteristic in that group or whether the outcome was the result of actual differences in the treatment. Random assignment will help to offset the likelihood of an imbalance related to participant characteristics.

WON'T PARTICIPANTS GET UPSET IF THEY DON'T GET THE ASSIGNMENT THEY WANT?

This is almost always a risk that participants take when they sign up for a clinical trial. In order to protect the rights of participants, rigorous reviews are conducted by uninvolved parties (for example, a local review board that must approve all research projects) to ensure that participants are made aware of the potential benefits as well as risks of participating in each trial before signing up. This may not prevent disappointment in all cases, however, it helps to remind participants that they will continue to receive all of the services they would have gotten if they decided not to participate in the trial, plus they will be compensated for the extra time they take to fill out the study questionnaires.

WHO SHOULD I TALK TO ABOUT QUESTIONS OR PROBLEMS WITH THE STUDY?

The research assistant working at your agency can help you with answers to questions about the study, or can refer you to the appropriate person who can answer your questions.

WHAT SHOULD I TELL CLIENTS ABOUT THE CLINICAL TRIALS NETWORK AND THE MOTIVATIONAL INCENTIVES STUDY?

The Clinical Trials Network has developed informational brochures for clients interested in participating in clinical trials. You should familiarize yourself with these brochures so that you can answer questions and refer participants and potential participants to the right sources. *What are Clinical Trials?* is an excellent source for understanding the benefits of participating in a research study. *Should I join the Motivational Incentives Study?* is a brochure for clients that describes this study in

terms that are easily understood. More details about the study can be found in the *Informed Consent Form* that the research assistant will review with a client who is deciding whether or not to participate. In addition, you will receive training in how to talk with the clients about the research project. If you ever find yourself unable to answer a question about the research, you should turn to your supervisor, the Research Assistant, Node Coordinator, or an Investigator for more information.

For more information on the National Drug Abuse Treatment Clinical Trials Network, visit the NIDA website at www.nida.nih.gov or www.drugabuse.gov.

For information on other clinical trials, the National Institutes of Health (NIH) has created a website to help patients, family members, and the general public obtain information about government sponsored clinical trials. You may log on to www.Clinicaltrials.gov to learn about ongoing or new trials for all types of health related conditions. The descriptions for individual trials include eligibility criteria, purpose of the trial, location, and how to apply if interested. The website is maintained and updated regularly by the National Library of Medicine.

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Clinical Trials Network



MOTIVATIONAL INCENTIVES

A research study on new ways to help people remain abstinent

FOR CLINICIANS

The agency you work for has agreed to participate in a clinical trial to study a behavioral intervention using *Motivational Incentives*. This pamphlet provides an overview of this intervention and some answers to questions you might have as a clinician participating in this research project. More information about clinical trials can be found in the National Drug Abuse Treatment Clinical Trials Network (CTN) brochure, *What are Clinical Trials?*

WHAT IS THE STUDY ABOUT?

The purpose of this study is to develop and evaluate, in a community treatment setting, motivational incentive procedures that have documented efficacy in a variety of treatment research clinics. The study will determine if Motivational Incentives along with Standard Care therapy is more effective than Standard Care therapy alone for the treatment of clients using stimulant and other drugs of abuse.

WHAT ARE MOTIVATIONAL INCENTIVES?

Incentives refer to things that increase a desired behavior. For example, giving your child an allowance for doing chores is an incentive because the allowance increases the likelihood he or she will keep doing chores. In some cases incentives are not tangible; praise from your supervisor may be an incentive to work harder. This study is called Motivational Incentives because participants may receive tangible prizes for providing urine and breath samples that are drug-negative. We hope that the incentives, provided early in treatment, may help increase clients' motivation to keep coming to treatment and to stay clean.

ISN'T THIS A BIT LIKE BRIBING PEOPLE TO STOP USING DRUGS?

Not really. Incentives work by increasing the occurrence of a desired behavior, such as coming to treatment and staying clean. Once clients start coming to treatment and staying clean, their motivation to continue to do so may increase. As a therapist, you know that clients need to come to treatment to get and stay clean long term. The tangible incen-

tives may increase the number of clients who stick with treatment a little bit longer, who then can derive all the benefits that treatment provides. Therefore, the participant and therapist together must explore behaviors that support abstinence. The incentives simply give clients additional support for choices that result in a drug free urine.

WHAT ROLE DO THE RESEARCH ASSISTANTS PLAY IN THE STUDY?

The research assistants will carry out all functions related to the study. This includes:

- * Screening potential participants
- * Obtaining informed consent from participants
- * Conducting research intake procedures
- * Randomizing and assigning participants to their study condition
- * Collecting and testing urine samples
- * Purchasing and tracking incentives
- * Conducting the drawings for prizes
- * Tracking participants during treatment and for follow-up
- * Conducting follow-up interviews

WHAT ROLE DO I PLAY IN THE STUDY?

Since everyone who participates in the study will get Standard Care therapy (that is, treatment as usual), clinicians will provide all of the services and support that are typical in the normal day-to-day operation of this clinic, such as:

- * Encourage participants to continue providing urine samples and to remain abstinent from all drugs of abuse
- * Work with participants to build lifestyle changes during periods of abstinence
- * Maintain accurate records of treatment contacts and progress

In addition, since about half of your clients will be randomly assigned to get Motivational Incentives along with Standard Care therapy, only some will get the chance to earn incentives for

abstinence. The study is trying to determine what effect those incentives have on rates of retention and abstinence, so it is important that you treat all study participants, regardless of treatment assignment, as similarly as possible.

IS THERE ANYTHING I NEED TO DO DIFFERENTLY FROM WHAT I DO NOW?

Because you are in the position of knowing these participants well, your assistance and input is invaluable for the success of this study. Your assistance and input is needed in the following ways:

- * Witness the informed consent process whenever possible
- * Be present at each drawing whenever possible
- * Suggest tangible incentives for the participants to choose from
- * Occasionally operate the incentive program if the research assistant is unavailable

After this study ends, we will be looking for other incentives for clients. This is where your help is really needed. We need therapists to be thinking of very low and no-cost incentives that clients may want for future studies, or as part of standard treatment. The study coordinators will be speaking with you before, during and after the study to get your impressions of how things are working and other incentives that therapists can use to motivate behavior change.

WHY DO YOU RANDOMLY ASSIGN PARTICIPANTS?

In order to make sure that the characteristics of the participants in the study are balanced, random assignment is necessary. Imagine some of the possible situations that could happen if participants were allowed to pick which assignment they preferred. More people of a certain gender, or race, or level of drug use could choose one intervention over the other. In such a situation, when statisticians analyze the research results it would be hard to tell whether differences between the Motivational Incentives group and the Standard Care group were the result of so many participants